Loratadine Syrup Hives Relief

Container Labeling

(4 fl oz) OTC (1/25/05)

Container Labeling – 4 fl oz (OTC) (1/25/05)

Main Panel

Silarx Logo NDC 54838-538-40 Original Prescription Strength

Non-Drowsy *
Loratadine Syrup
Hives Relief

Loratadine 5 mg/5 mL
Antihistamine
Relief of Itching Due to Hive
Fruit Flavored Syrup

24 hour

* When taken as directed See Drug Facts Panel

120 mL (4 FL OZ)

Loratadine Syrup Comparative Container Labeling – 4 fl oz (OTC)

(1/25/05)

Side Panels

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding, ask a health

professional before use.

Keep out of reach of children. In

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

SEE CARTON FOR FULL WARNINGS.

Directions

- adults and children 6 years and over: 2 teaspoonfuls daily
- do not take more than 2 teaspoonfuls in 24 hours

Other information

- SAFETY SEALED: Do not use if imprinted seal around cap of bottle is broken or missing.
- Store between 2° and 25°C (36° and 77°F)

Manufactured by: Silarx Pharmaceuticals, Inc. Spring Valley, NY 10977 USA ISS:01/2005

Control # Exp. Date:

Loratadine Syrup Hives Relief

Carton Labeling

(4 fl oz) OTC (Revised 1/25/05)

Carton Labeling (4 fl oz) OTC (Revised 1/25/05)

Front Panel

Silarx Logo

NDC 54838-538-40
Original Prescription Strength

Non-Drowsy *

Loratadine Syrup Hives Relief

Relief of Itching Due to Hive
Loratadine 5 mg/5 mL
Antihistamine
Fruit Flavored Syrup

24 hour

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120 mL (4 FL OZ)

Carton Labeling – 4 fl oz (OTC) (Revised 1/25/05)

Right - Side Panel

Drug Facts

Active ingredient (in each 5 mL) Purpose
Loratadine 5 mg Antihistamine

Uses

 relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine**. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to prevent hives from any known cause such as:
- foods
- insects stings
- medicines
- latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

• if you have ever had an allergic reaction to this product (loratadine) or any of its ingredients

Carton Labeling – 4 fl oz (OTC) (Revised 1/25/05)

Left - Side Panel

Drug Facts (continued)

Ask a doctor before use if you have

- liver or kidney disease. Your doctor should determine if you need a different dose.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Get medical help right away
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions	
. adults and children 6 years and over	2 teaspoonfuls daily; do not take more
	than 2 teaspoonfuls in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney	ask a doctor
disease	

Other information

- SAFETY SEALED. Do not use if imprinted seal around cap is broken or missing
- Store between 2° and 25°C (36° and 77°F)

Inactive ingredients

citric acid, edetate disodium, flavor, glycerin, propylene glycol, sodium benzoate, sugar, water.

Manufactured by:

Silarx Pharmaceuticals, Inc.

Spring Valley, NY 10977 USA

SAVE THIS CARTON FOR FULL LABELING INFORMATION.

Bar Code (54838-538-40)

Carton Labeling – 4 fl oz (OTC) (Revised 1/25/05)

Back Panel

Silarx Logo NDC 54838-538-40 Original Prescription Strength

Non-Drowsy *
Loratadine Syrup
Hives Relief

Relief of Itching Due to Hive
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